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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,245	02/12/2004	Thomas Antonsson	3764-153	4185

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,245	ANTONSSON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-38,47-49 and 52-65* is/are pending in the application.

4a) Of the above claim(s) *47-49 and 59-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-38 and 52-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/776,231.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-38, 47-49 and 52-65 are pending.

Applicants' amendment filed January 25, 2007 is acknowledged. Applicants' response has been fully considered. Claims 1, 6, 10, 14, 17, 21, 26, 28, 30 and 53 have been amended, and claim 2 has been cancelled. Claims 47-49 and 59-65 are non-elected inventions and withdrawn from consideration. Therefore, claims 1, 3-38 and 52-58 are examined.

Information Disclosure Statement (IDS)

2. The IDS filed January 31, 2007 is acknowledged, and the references have been considered (see attached).

Withdrawn Claim Objections

3. The previous objection to claim 1 is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 16 in the amendment filed January 25, 2007.

Withdrawn Claim Rejections - 35 USC § 101

4. The previous rejection of claim 1 under 35 U.S.C. 101, is withdrawn in view of applicant's amendment to the claim, and applicants' response at page 16 in the amendment filed January 25, 2007.

Withdrawn Claim Rejections - 35 USC § 112

5. The previous rejection of claims 1-38, 53, 56 and 58 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 17-18 in the amendment filed January 25, 2007.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

6. The previous rejection of claim 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 and 45 of U. S. Patent 6,262,028, is withdrawn in view of applicant's cancellation of the claim in the amendment filed January 25, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-5, 8, 13-23, 26-30, 33-38, 53 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1, 3-5, 8, 13-23, 26-30, 33-38, 53 and 56-58 are indefinite because claim 1 recites R^1 represents $-R^3$ or $-A^1C(O)N(R^4)R^5$ or $-A^1C(O)OR^4$, and A^1 represents C_{1-5} alkylene in lines 5-6, however, the claim also recites when R^1 represents $-A^1C(O)N(R^4)R^5$, A^1 represents C_{1-3} alkylene in line 24, thus it is not clear whether A^1 is C_{1-5} alkylene or C_{1-3} alkylene. Claims 3-5, 8, 13-23, 26-30, 33-38, 53 and 56-58 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

9. Claim 57 recites the limitation "separate ...use" in line 2. There is insufficient antecedent basis for this limitation in the claim, because the independent claim, claim 1 recites a pharmaceutical formulation having the combination of components (a) and (b), thus, these two components are suitable for combination use, not in separate use. Claim 58 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim

from which they depend. Claim 58 is also indefinite because the claim does not further limit claim 53, since claim 53 recites a combination comprising components (a) and (b), which is the same as component (a) is combined with component (b).

Response to Arguments

Applicants indicate the combination as claimed in claim 53 could also be "suitable for" separate use and therefore sufficient basis appears for this language. Claim 38 of U.S. Patent 6,984,627 reciting a language similar to this appears and was found to be acceptable (page 18 of the response)

Applicants' response has been considered, however, the argument is not found persuasive because claim 57 is now dependent from claim 1, which recites a pharmaceutical formulation comprising the two components, and a pharmaceutical formulation cannot be used separately. Thus the rejection is maintained.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3-38 and 52-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 and 45 of U. S. Patent

6,262,028. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3-38 and 52-58 in the instant application disclose a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 and R^2 are defined; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. This is obvious variation in view of claims 1-39 and 45 of the patent which disclose a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier; and a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and the specification discloses the compounds of invention may be combined and/or co-administered with an antiplatelet agent such as acetylsalicylic acid (column 11, lines 16-37). Both sets of claims cite a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. Thus, claims 1, 3-38 and 52-58 in present application and claims 1-39 and 45 in the patent are obvious variation of a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$.

11. Claims 1, 10-13, 31-35, 37 and 52-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U. S. Patent

5,965,692 (mistakenly written as 6,262,028 in the previous Office Action). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 10-13, 31-35, 37 and 52-58 in the instant application disclose a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 can be H or $C_{1\text{-}10}$ alkyl, and R^2 can be OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$. This is obvious variation in view of claims 1-14 of the patent which disclose a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a pharmaceutical formulation including a compound of formula I or a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier; and the specification discloses the compounds of invention may be combined and/or co-administered with an antiplatelet agent such as acetylsalicylic acid, and an effective doses (i.e., 0.001-100 mg/kg body weight) of the compound of formulation I can be used in the treatment (column 10, lines 42-65). Both sets of claims cite a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$ in the formulation. Thus, claims 1, 10-13, 31-35, 37 and 52-58 in present application and claims 1-14 in the patent are obvious variation of a pharmaceutical formulation comprising an effective amount of acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$, where R^1 is H or $C_{1\text{-}10}$ alkyl, and R^2 is OH; and a combination comprising acetylsalicylic acid and a compound of formula I, $R^1O(O)C\text{-}CH_2\text{-}(R)Cgl\text{-}Aze\text{-}Pab\text{-}R^2$ in the formulation.

Response to Arguments

Applicants indicate a Terminal Disclaimer will be submitted when an indication of allowability is received in this case and it is confirmed that obviousness-type double patenting still exists with respect to the claims as allowed.

Applicants' response has been considered, and the rejection is maintained.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
April 4, 2007